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Arizona State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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License and Permit Renewal

The deadline for renewing biennial licenses and permits that **end with an odd number** (not an unusual number but an odd number, as opposed to an even number) is November 1, 2001. In addition to this renewal reminder, please be aware that continuing education credits required for relicensure as a pharmacist are to be completed within the 24 months immediately prior to renewing your license. Again this year, a random audit of approximately 10% of the pharmacists renewing their license will be conducted. This process requires the applicant to submit proof of continuing professional education, including 3.0 hours of pharmacy law, not necessarily Arizona pharmacy law. Pharmacy law is available from a variety of sources that are American Council on Pharmaceutical Education (ACPE)-approved. One can identify an approved ACPE pharmacy law continuing education program if the last two digits in the universal program number are "03." Only ACPE or Arizona State Board of Pharmacy approved continuing pharmacy education is acceptable in meeting the requirements for license renewal.

Another "heads-up" relating to license/permit renewals: if you **do not** receive a renewal notice by October 10, 2001, call the Board office and ask to speak to one of the licensing staff. Sometimes we "goof up," but more often the cause for not receiving a renewal notice is that someone has moved and neglected to tell the Board office his or her new address. Notifying the Board of a new home address or place of practice within 10 days is a requirement (see R4-23-405, 608; ARS-32-1926).

Note: the Board of Pharmacy is **not** responsible for providing a renewal notice, but we continue to extend this courtesy to our registrants. However, please keep in mind that it is the pharmacist, or permit holder who is responsible for a timely renewal of the license or permit.

Controlled Substance Note

On August 16, 2001, the Drug Enforcement Administration issued the final rule notice that **dichloralphenazone, its salts, isomers, and salts of isomers are placed in controlled substance class four (C-IV).** The most widely known product impacted by this change is "Midrin®." Obviously, this change also impacts any generic or other brand name drug that contains **dichloralphenazone**. If you have not already added these items to your controlled substance inventory, you should put this *Newsletter* down now and "just do it." Your friendly Board of Pharmacy compliance officer will commend you for your efficiency.

Administrative Rules

R4-23-110, 202, 203, 204, 205, 404, 405, 406, 407, and 409 were recently presented to the Governor's Regulatory Review Council (GRRC) for publication. These rule-making packages include increases in fees for the renewal of pharmacy and pharmacist license/permits. Pharmacist licenses will increase from $110 to $145 for two (2) years and pharmacy permits increase from $300 to $400 for two (2) years. **Changes do not impact the 2001 renewal.** These fee increases are the first in 15 years and are prompted by the need to increase our staff to accommodate the expanding pharmacist and pharmacy community in Arizona. The majority of the other changes are format and style modifications to comply with present rule drafting protocol. One exception: **pharmacy interns** will be permitted to give and receive prescription telephone transfers.

Also submitted to GRRC for consideration are the following Board rules: R4-23-604, 606, 607, 608, 611, and 612. As in the rules mentioned above, the majority of proposed changes in these sections are style and format modifications to improve conciseness and understandability. In the case of the drug manufacturing rules, a dramatic reduction in the wordiness and length was possible as a result of referencing the federal current good manufacturing practices as our state standards.

FYI: The best source for up-to-date information relevant to the Board of Pharmacy rule making, statute changes, or policy statements is the Board's Web site at www.pharmacy.state.az.us. The Web site also contains useful links to several pharmacy information sources. Try it, you'll like it!

Levothyroxine Sodium (LT4)

Your editor has attempted to keep readers apprised of the US Food and Drug Administration (FDA) approval and generic substitution status of LT4. Information received at the Board office from both ***Pharmacist's Letter*** *(with credit to a July 12, 2001 FDA Talk Paper)* **and Abbott Laboratories** within the past two weeks is summarized and provided as an educational information service to our readers. Briefly, on August 14, 1997, the FDA stated that oral LT4 products were considered **"new drugs,"** and, as such, their manufacturers were required to file a new drug application (NDA). A deadline of April 26, 2000 was set and then extended to August 14, 2001 for filing NDAs. Other options included filing a "citizens petition" requesting an exemption from the NDA process. Two firms filed NDAs promptly and received FDA approval. Unithroid® and Levoxyl® were approved August 21, 2001 and May

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25, 2001 respectively. Both these products are FDA-approved, LT4 oral medications. This approval is a marketing approval only; at this time, there are no bioequivalency or bioavailability ratings published by FDA. In other words, **no generic substitution of these two approved drugs is allowed.** Another frequently prescribed LT4 drug, **Synthroid®**, at the time of this writing, is not FDA-approved; however, the new owner of Synthroid, Abbott Laboratories, has filed a timely (prior to August 14, 2001) NDA for its product. Pursuant to FDA provisions for NDAs filed prior to August 14, 2001 and not approved by that date, a prescribed "distribution phase-out" is established. Knowledgeable sources predict that Synthroid will receive FDA approval well in advance of the time when the "phase-out" would impact product availability. It is anticipated that the approval of the NDA for Synthroid will result in having three LT4-approved products with no bioequivalency or bioavailability ratings, and, therefore, no approved generic substitution among the three. For now: **do not** substitute LT4s.

Kudos

The following Arizona pharmacists have recently been awarded the Certified Geriatic Pharmacist credential by the Commission for Certification in Geriatic Pharmacy: Mary Garvey, Elizabeth Libby, Thomas Martin, and Bruce Patterson. Congratulations to these ambitious colleagues as they expand their knowledge and their value in the health care field.

Disciplinary/Reinstatement Actions

Board of Pharmacy

Jeanmarie Hazzard, RPh #8234, license suspended, required to enroll in Pharmacists Assisting Pharmacists of Arizona (PAPA), may appear after July 13, 2001, to request reinstatement of license on probation.

Albertson's #983, #955, and **#969,** fined $37,500, outdated over-the-counter items on shelves after multiple notices from Board.

Osco #2018 fined $99,000, outdated over-the-counter (OTC) items on shelves after multiple notices from Board.

John S. Bacovcin, RPh #8306, license suspended five years, may appear after May 17, 2002, to request reinstatement.

Roadrunner Pharmacy permit #3158, fined $1,000 and placed on one-year probation, violation of R4-23-410.

Board of Dental Examiners

Jesse DeBaker License, #5069, voluntarily surrendered license on March 10, 2001.

Board of Medical Examiners

Philip M. Sorensen, #18503, voluntarily surrendered license on June 21, 2001.

Susan E. Barlow, #24702, may not practice medicine or issue prescriptions as of June 22, 2001.

John B. Flynn, #14019, voluntarily surrendered license on May 23, 2001.

Robert Bierenbaum, #23508, voluntarily surrendered license on April 30, 2001.

Allan D. Belden, #10021, voluntarily surrendered license on April 30, 2001.

E. Charles Black, MD #11485, effective August 14, 2001, controlled substance prescribing for C-II and C-III drugs is reinstated.

William W. Pollard, MD #19183, effective August 17, 2001, medical license surrended.

Board of Osteopathic Examiners

Dale Wheeland, DO #2018, prescribing privileges are fully reinstated effective May 12, 2001.

Lillian D. Puma, DO #2836, may not prescribe Schedule II controlled substances until further notice.

Notice: Before making a prescription-dispensing or any patient-care decision pursuant to information in this issue, you are encouraged to verify the current status of a license with the appropriate licensing agency (board).

For information relating to rehabilitation of drug- or alcohol-impaired pharmacists or pharmacy interns, contact **Pharmacists Assisting Pharmacists of Arizona (PAPA)** at 480/838-3668.

The *Arizona State Board of Pharmacy News* is published by the Arizona State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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